

REMARKS

DOUBLE-PATENTING REJECTION

On page 3 of the Office Action, the Examiner states that

“Applicant has failed to adequately respond to the previous double patenting rejection set forth in the prior Office Action Accordingly, the rejection is maintained and reiterated herein.”

In response, Applicant draws attention to the terminal disclaimer filed on July 9, 2007.

SECTION 112 REJECTION

Applicant cancels claims 53-55. Accordingly, the section 112 rejection is moot.

INTERVIEW SUMMARY

Applicant appreciates the Examiner's consideration at the telephone interview of January 14, 2008 at which were discussed claim 1 and *Hayes*.

At the interview, the Examiner indicated that any catheter, such as that shown in *Hayes*, that followed the curve of a blood vessel would be capable of resiliently assuming a preferred shape (i.e. the shape of the blood vessel).

When asked whether outside of the blood vessel, the *Hayes* catheter could be regarded as resiliently assuming a preferred shape, the Examiner replied in the affirmative. The Examiner then explained that this was because under such circumstances, the catheter would remain whole, and not disintegrate.

At the interview, the Examiner's position appeared to be that:

1. Any solid object that does not spontaneously disintegrate is an object that “assumes a preferred shape,”
2. Conversely, any solid object that spontaneously disintegrates is not an object that “assumes a preferred shape.”

Applicant disagreed with the foregoing position because, if accepted, it would be impossible to identify any solid object whatsoever that does *not* "assume a preferred shape." By definition any such object would have long ago disintegrated, leaving behind a universe filled only with objects that manage to "resiliently assume a preferred shape." Given the unreasonable breadth on the Examiner's interpretation of the words "resiliently assume a preferred shape," no agreement could be reached.

CLAIM AMENDMENTS

At the interview, the Examiner suggested that the claims be amended to recite additional structure. In response, Applicant amends claim 1 to recite

a pre-formed probe stored within a cannula that defines an axis, the probe, when deployed from the cannula, resiliently assuming a preferred shape having a natural bend that urges the probe outward, away from the axis of the cannula,

The remaining independent claims are amended along the same lines. Support for the foregoing amendment can be found at the specification on page 7, lines 11 to 16:

The probe **16** is pre-formed so that a natural bend urges it outward, away from the axis of the cannula **60**. As a result, when the probe **16** is extended out its housing **59** and beyond the distal end of the cannula **60**, this natural bend places the atraumatic light-coupler **24** of the fiber **18** in contact with the arterial wall **14** distal to the cannula **60**.

Applicant submits that one of ordinary skill in the art who has read the specification would understand "a preferred shape" to mean a shape that an object assumes at static equilibrium. In particular, one of ordinary skill in the art would recognize that

1. All objects have a first shape at static equilibrium.
2. In response to an external force, an object assumes a second shape other than the aforementioned first shape at static equilibrium.
3. In response to removing that external force,

- a. some objects remain in the second shape, whereas
- b. other objects revert from the second shape back to the first shape.

Applicant further submits that one of ordinary skill in the art would have no difficulty understanding an object that “resiliently assumes a preferred shape” to be an object corresponding to (3b).

Applicant further amends the claims to recite the structural limitation that the preferred shape, i.e. the shape at static equilibrium, be one that has a natural bend that urges the probe outward, away from the axis of a cannula.

SECTION 102 REJECTION OF CLAIM 1, 43, AND 46

The foregoing amendment clearly distinguishes over *Hayes*.

Hayes fails to disclose any probe that is pre-formed and that, when deployed from a cannula, resiliently assumes a preferred shape having a natural bend that urges the probe away from the cannula.

As shown in FIGS. 17A and 17B of *Hayes*, the deflecting wires 162 are used to pull the probe *away* from the guide wire 150 so that the probe tip can contact the wall of the lumen. This indicates that the probe has no natural outward bend, since if it did, there would be no need to use the deflection wires 162 to pull the probe tip into contact with the wall of the lumen. If the *Hayes* probe actually had a natural outward bend as recited in the claim, the probe tip would naturally come into contact with the wall of the lumen without requiring the assistance of a deflection wire 162.

In addition, inspection of the figures makes it plain that the *Hayes* probe is in no way “stored within a cannula” as required by the claim. Instead, the guide wire 150 guides the unsheathed *Hayes* probe through the vasculature.

In fact, none of the figures in *Hayes* show any structure that could be regarded as a cannula from which the probe might be deployed. Since *Hayes* does not teach any sort of cannula from which the probe can be deployed, it cannot possibly teach a probe that “when deployed from the cannula resiliently” assumes “a preferred shape having a natural bend that urges the probe outward,” as required by claim 1.

Similar arguments apply to the remaining independent claims: claim 43 and 46.

SECTION 102 REJECTION OF CLAIM 57 AND 61

In the interview of January 14, 2008, the Examiner stated that the atraumatic light coupler was regarded as including both the optical shield 12 and the body of air contained within a hollow defined by that shield. The Examiner’s position at that time was that since *Hayes*’ optical fiber was clearly in contact with that air, it followed that it was in contact with the atraumatic coupler as defined.

Claim 57 was drafted specifically to require that the *surface* of the atraumatic light coupler be in contact with the optical fiber. Since the air contained within the *Hayes* optical shield 12 does not have a *surface*, claim 57 cannot be anticipated.

Claim 61 recites a limitation similar to claim 57 and is therefore patentable for at least the same reasons.

SECTION 102 REJECTION OF CLAIM 56

In the interview of January 14, 2008, the Examiner stated that the atraumatic light coupler was regarded as including both the optical shield 12 and the body of air contained within a hollow defined by that shield. The Examiner’s position at that time was that since *Hayes*’ optical fiber was clearly in contact with that air, it followed that it was in contact with the atraumatic coupler as defined.

The Examiner further explained at that interview that if the hollow defined by the shield 12 were evacuated of all air, then the optical fiber would no longer be regarded as being “in

contact with" the atraumatic light coupler because there would be no air between the shield **12** and the fibers to provide a medium for such contact.

Applicant submits that:

1. *Hayes* does not teach that the hollow defined by the shield is in fact filled with air, and, in the alternative,
2. It is unreasonable to regard the air contained within the shield **12** as being part of the atraumatic coupler.

With regard to (1), a section 102 rejection requires that each and every claim limitation be taught by the reference. Since *Hayes* does not specifically state that the hollow defined by the shield is in fact filled with air, the section 102 rejection is improper.

Moreover, there are many technical reasons why one might wish to evacuate the hollow. For example, if the hollow were filled with air, there may be condensation, unless one took additional steps to fill the hollow with suitably dry air. In addition, an air filled hollow would cause the shield to experience forces caused by changes in pressure. Over the long term, such forces would distort the shield, thus altering its optical properties, or they would eventually loosen the shield, perhaps causing it to leak. In addition, air has optical properties that differ from those of a vacuum. Such optical properties may be affected by changes in temperature and pressure. Given these facts, one cannot simply assume, as the Examiner has done, that the hollow defined by the shield **12** is filled with air.

With regard to (2), claim 1 requires that the atraumatic light-coupler "atraumatically contact the intraluminal wall when the probe resiliently assumes a preferred shape."

Any structure that corresponds to claim 1's atraumatic light-coupler should at least have the properties set forth in the claim. In particular, before a structure in *Hayes* can reasonably be

regarded as an atraumatic light coupler, it must, at the very least, contact the intraluminal wall when the probe resiliently assumes its preferred shape.

The optical shield 12 can clearly be regarded as meeting this limitation. But the air within the hollow defined by the optical shield does not. That air never contacts the intraluminal wall, either atraumatically or otherwise. Therefore, there is no basis for regarding that air as being a part of the atraumatic light coupler.

The Examiner may not arbitrarily expand the structure designated as an atraumatic light coupler beyond what is necessary to carry out the function of that coupler. Otherwise, the Examiner would be free to regard even the optical fibers as part of the atraumatic light coupler, despite the fact that the fibers do not carry out the function of the atraumatically contacting the intraluminal wall. In fact, there would be no limit to how the Examiner could define an atraumatic light coupler.

SECTION 102 REJECTION OF CLAIM 59

Claim 59 recites the further limitation that the atraumatic light coupler be “disposed along a side of the probe.”

The Examiner has not indicated, in the Office Action, where *Hayes* teaches this claim limitation. Nor has Applicant been able to identify any such teaching in *Hayes*. As best understood, any structure in *Hayes* that could reasonably be regarded as an atraumatic light coupler is at the distal tip of the probe, and not at the side of the probe as required by claim 59.

CONCLUSION

No fees are believed to be due in connection with the filing of this response. However, to the extent fees are due, or if a refund is forthcoming, please adjust our Deposit Account 06-1050, referencing Attorney Docket No. 12258-029001.

Applicant : Andres F. Zuluaga et al.
Serial No. : 10/602,345
Filed : June 23, 2003
Page : 13 of 13

Attorney's Docket No.: 12258-029001

Respectfully submitted,

Date: January 28, 2008



Faustino A. Lichauco
Reg. No. 41,942

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110
Telephone: (617) 542-5070
Facsimile: (617) 542-8906
21821381.doc